

Claims:

1. A monitoring device for use in conjunction with one or more body fluid testing devices to provide an indication of the time of maximum fertility in the mammalian ovulation cycle, wherein:

a) said one or more testing devices provide test signals readable by said monitoring device, including a signal proportional to the concentration of a first analyte in a body fluid, which first analyte exhibits a detectable concentration change at about the time of ovulation in said cycle, and a signal proportional to the concentration of a second analyte in a sample of body fluid, which second analyte exhibits a detectable concentration change after the commencement of said cycle but before the concentration change of said first analyte becomes detectable; and

b) in response to test signals provided by said one or more testing devices used in a series of tests conducted following the commencement of said cycle, said monitoring device provides an indication that fertility is elevated when said concentration change of said second analyte has been detected, and an indication that fertility is maximum when said concentration change of said first analyte has been detected.

2. A monitoring device according to claim 1 wherein said first analyte is luteinising hormone (LH).

3. A monitoring device according to claim 1 wherein said second analyte is selected from the group consisting of estradiol and metabolites thereof.

4. A monitoring device according the claim 3 wherein said second analyte is estrone-3-glucuronide (E3G).

5 5. A monitoring device according to claim 1 wherein said body fluid is urine.

6. A monitoring device according to claim 1 wherein said mammalian ovulation cycle is the human ovulation cycle.

10

7. A monitoring device according to claim 1 wherein no indication of maximum fertility is provided unless said concentration change of said second analyte has already been detected in the current cycle or is detected no later than
15 the time at which said concentration change of said first analyte is detected.

20 8. A monitoring device according to claim 1 comprising receiving means to receive a testing device, reading means associated with said receiving means to read said test signals, electronic processing means to interpret said test signals, and display means to provide said indications of fertility.

25 9. A monitoring device according to claim 8, wherein said display means includes a visual indication in the form of a bar or similar symbol the height or length of which is altered in either a continuous or step-wise manner as the likelihood of conception increases, attaining a maximum
30 height or length to indicate the most appropriate time in the cycle to attempt conception.

Sub AB 10. A monitoring device according to claim 1 including interface means to communicate with electronic data transmission means.

5 11. A monitoring device according to claim 10, wherein said electronic data transmission means is a semi-conductor memory device.

10 12. A test kit comprising a monitoring device according to claim 1 together with at least one body fluid testing device to provide said readable test signals.

15 13. A test kit comprising a monitoring device according to claim 1 together with a plurality of body fluid testing devices to provide said readable test signals.

20 14. A test kit according to claim 13 wherein each of said testing devices provides a test signal proportional to said concentration of said first analyte and a test signal proportional to said concentration of said second analyte.

15. A test kit according to 14 wherein each of said test devices uses a single sample of said body fluid.

25 16. A test kit to claim 15 wherein said ovulation cycle is the human ovulation cycle, said body fluid is urine, said first analyte is LH and said second analyte is E3G.

Sub AB 17. A method for determining the time of maximum fertility in the mammalian ovulation cycle, wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid to detect a change in the concentration of an analyte indicative of the actual event

of ovulation and wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid to detect a change in the concentration of an analyte indicative of the imminent event of ovulation.

5

18. A method for determining the time of maximum fertility in the human ovulation cycle, wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid obtained from an individual human subject to detect an elevated concentration of luteinising hormone (LH) indicative of the event of ovulation, wherein additional testing is conducted over a period of days in the current ovulation cycle on samples of body fluid obtained from the individual human subject to detect an elevated concentration of an analyte selected from the group consisting of estradiol and metabolites thereof indicative of the imminent event of ovulation.

19. A method according to claim 18, wherein an analyte selected from the group consisting of estradiol and metabolites thereof are detected in the same body fluid samples as are used in the LH tests.

20. A method according to claim 18, or claim 19, wherein an elevated LH concentration apparently indicative of the event of ovulation is disregarded unless an elevated concentration of an analyte selected from the group consisting of estradiol and metabolites thereof has already been detected in the current cycle or is detected concurrently with the elevated LH concentration.

~~21.~~ A method according to claims ~~17~~, ~~18~~ or claim ~~19~~,
wherein a single test is used to determine both LH and said

S3

-52-

an analyte selected from the group consisting of estradiol and metabolites thereof in a single body fluid sample.

Sub 5
A5 22. A test kit for use in a method according to claims 18 comprising:

10 a) at least one body fluid testing device that provides a readable signal proportional to the concentration of LH in a sample of said body fluid:

15 b) at least one body fluid testing device that provides a readable signal proportional to the concentration of said analyte selected from the group consisting of estradiol and metabolites thereof in a sample of said body fluid;

20 c) an electronic monitor having reading means to read said readable signals and incorporating computer means to interpret said readable signals and to determine therefrom in conjunction with data from previous body fluid tests whether the event of ovulation in the current cycle is about to occur or has just occurred.

22 23. A test kit according to claim 22, comprising a plurality of testing devices each of which provides a
25 readable signal proportional to said LH concentration and a readable signal proportional to said estradiol/metabolite concentration in a single sample of the body fluid.

Sub 30
A6 24. A test kit according to claim 22, wherein the electronic monitor includes interface means to communicate with electronic data transmission means.

54

(ii) downloading electronic data from said monitoring device onto said electronic data transmission means;

5 (iii) inputting said downloaded electronic data into computer means, from which computer means a health professional thereby derives patient-related information.

27 28. A method according to claim 27, wherein said electronic
10 data transmission is a semi-conductor memory device.

28 29. A method according to claim 27 wherein said first
analyte is luteinising hormone (LH).

29 30. A method according to claim 27 wherein said second
15 analyte is selected from the group consisting of estradiol and metabolites thereof.

30 31. A method according to claim 30 wherein said second
20 analyte is estrone-3-glucuronide (E3G).

31 32. A method according to claim 27 wherein said body fluid
is urine.

32 33. A method according to claim 27 wherein said mammalian
25 ovulation cycle is the human ovulation cycle.

33 34. A method according to claim 27, wherein in response to
test signals provided by said one or more testing devices
30 used in a series of tests conducted following the commencement of said cycle, said monitoring device provides an indication that fertility is elevated when said concentration change of said second analyte has been

detected, and an indication that fertility is maximum when said concentration change of said first analyte has been detected.

- 34 33
5 35. A method according to claim 34 wherein no indication of maximum fertility is provided unless said concentration change of said second analyte has already been detected in the current cycle or is detected no later than the time at which said concentration change of said first analyte is
10 detected.

46 AS
15 36. A method according to claim 27, wherein said monitoring device includes display means to provide an indication of fertility, said display means including a visual indication in the form of a bar or similar symbol the height or length of which is altered in either a continuous or step-wise manner as the likelihood of conception increases, attaining a maximum height or length to indicate the most appropriate time in the cycle to attempt conception.

26
20 37. A method according to claim 27 wherein each of said testing devices provides a test signal proportional to said concentration of said first analyte and a test signal proportional to said concentration of said second analyte.

37 36
25 38. A method according to claim 37 wherein each of said test devices uses a single sample of said body fluid.

38 26
30 39. A method according to claim 27 wherein said ovulation cycle is the human ovulation cycle, said body fluid is urine, said first analyte is LH and said second analyte is E3G.

-56-

26/ 40. A method according to claim 26/ for determining the time of maximum fertility in the mammalian ovulation cycle, wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid to detect a change in the concentration of an analyte indicative of the actual event of ovulation and wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid to detect a change in the concentration of an analyte indicative of the imminent event of ovulation.

40 41. A method according to claim 26/ for determining the time of maximum fertility in the human ovulation cycle, wherein testing is conducted over a period of days in the current ovulation cycle on samples of body fluid obtained from an individual human subject to detect an elevated concentration of luteinising hormone (LH) indicative of the event of ovulation, wherein additional testing is conducted over a period of days in the current ovulation cycle on samples of body fluid obtained from the individual human subject to detect an elevated concentration of an analyte selected from the group consisting of estradiol and metabolites thereof indicative of the imminent event of ovulation.

41 42. A method according to claim 41, wherein an analyte selected from the group consisting of estradiol and metabolites thereof are detected in the same body fluid samples as are used in the LH tests.

42 43. A method according to claim 41 or claim 42 wherein an elevated LH concentration apparently indicative of the event of ovulation is disregarded unless an elevated concentration of an analyte selected from the group consisting of

57

estradiol and metabolites thereof has already been detected in the current cycle or is detected concurrently with the elevated LH concentration.

- 43
5 44. A method according to claim 41 or claim 42, wherein a single test is used to determine both LH and said an analyte selected from the group consisting of estradiol and metabolites thereof in a single body fluid sample.
- 44
10 45. A method according to claim 26, wherein said electronic data transmission means is selected from the group consisting of a smart card and a floppy disk.
- 45
15 46. A method according to claim 27, wherein said electronic data transmission means is interfaced with said monitor to record an event occurring during an ovulation cycle.
- 46
20 47. A method according to claim 46, wherein said event is an act of intercourse.
- 47
25 48. A method according to claim 46, wherein said event is the occurrence of a physiological symptom.
- 48
30 49. A method according to claim 27, wherein said electronic data transmission means is interfaced with said monitor to download a result of a specific test for which a specific testing device is provided.
- 49
50. A method according to claim 49, wherein said specific test is a test for an analyte selected from the group consisting of human chorionic gonadotrophin (hCG), pregnanediol-3-glucuronide (P3G) and follicle stimulating hormone (FSH).

24 25. A test kit according to claim 24²³, wherein said electronic data transmission means is selected from the group consisting of a smart card and a floppy disk.

5 25 26. A test kit according to claim 24²³, wherein said electronic data transmission means is a semi-conductor memory device.

Sup 10 A7 27. A method of patient management comprising:

(i) providing:

15 a) one or more testing devices that provide test signals, including a signal proportional to the concentration of a first analyte in a body fluid, which first analyte exhibits a detectable concentration change at about the time of ovulation in said cycle, and a signal proportional to the concentration of a second analyte in a sample of body fluid, which second

20 analyte exhibits a detectable concentration change after the commencement of said cycle but before the concentration change of said first analyte becomes detectable;

25 b) a monitoring device comprising receiving means to receive one of said one or more testing devices, reading means associated with said receiving means to read said test signals, electronic processing means to interpret said test signals, and interface means to communicate with electronic data transmission means; and

30 c) electronic data transmission means;